510(k) SUMMARY PER 21 CFR 807.92

FEB - 6 2014

510(k) Number: K140036

GENERAL INFORMATION:

Manufacturer:

Aptus Endosystems, Inc.
271 Gibraltar Drive
Sunnyvale, CA 94089
Tel: (408) 530-9050
Fax: (408) 530-9051

Contact Person:

Burt Goodson
Director, Scientific and Regulatory Affairs

Date Prepared:

February 3, 2014

DEVICE DESCRIPTION:

The Heli-FX EndoAnchor System comprises the EndoAnchor with EndoAnchor Cassette, the Heli-FX Applier, and the Heli-FX Guide.

Generic/Common Name and Classification:

Endovascular suturing system (OTD) per 21 CFR 870.3460

Trade Name:

Aptus Heli-FX EndoAnchor System

- Aptus EndoAnchor with EndoAnchor Cassette
- Aptus Heli-FX Applier
- Aptus Heli-FX Guide

PREDICATE DEVICES:

- Aptus Heli-FX EndoAnchor System per K102333
- Aptus Heli-FX Thoracic EndoAnchor System per K121168
- Aptus Heli-FX EndoAnchor System and Heli-FX Thoracic EndoAnchor System per K130677

INTENDED USE:

The Heli-FX EndoAnchor System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.

The EndoAnchor may be implanted at the time of the initial endograft placement, or during a secondary (i.e., repair) procedure.

PRODUCT DESCRIPTION:

The Heli-FX EndoAnchor System comprises the EndoAnchor implant (an intravascularly-applied suture, supplied in a Cassette containing 10 EndoAnchors), the Heli-FX Applier (a catheter-based device for placement of the EndoAnchor), and the Heli-FX Guide (a deflectable sheath to position the Applier).

The Aptus EndoAnchor is an endovascularly-placed suture designed to attach aortic endografts to the native vessel wall. The EndoAnchor is manufactured from medical-grade nickel-cobalt wire and is wound in a helical shape. The leading end is sharpened to a conical point to act as an integral needle facilitating atraumatic deployment through the graft material and vessel wall. The proximal end of the EndoAnchor includes a diagonal crossbar, which functions as a suture anchor designed to prevent over penetration of the EndoAnchor. Ten (10) EndoAnchors are pre-packaged into a cassette, which is supplied sterile to the user. The cassette is designed to facilitate easy and accurate loading of the EndoAnchor into the Applier catheter.

The Heli-FX Applier is designed to implant the Aptus EndoAnchor. The Applier implants one EndoAnchor at a time, and can be used to implant multiple EndoAnchors in a single patient. The Applier is designed for use with the Heli-FX Guide. The Applier is a 12Fr (OD) catheter with an integrated control handle. Two Applier lengths are available for anchoring in different regions of the aorta.

The Heli-FX Guide is a sterile, single use, disposable device designed to direct the Heli-FX Applier to the desired location for EndoAnchor implantation. The device is compatible with a 0.035" guide wire. The Heli-FX Guide consists of a 12 Fr-compatible (inner diameter) guide sheath with integrated control handle, and a matching 12 Fr OD obturator. Deflection of the distal tip of the catheter is accomplished by rotating the Control Knob located on the control handle. The Guide is available in both 62cm (16Fr OD) and 90cm (18Fr OD) working lengths. Multiple deflectable tip lengths are available to accommodate a range of aortic diameters. The Obturator is used during vessel access and is designed to follow the guide wire and provide access through tortuous vasculature.

SPECIAL CONTROLS:

Special controls have been established for endovascular substring systems per 21 CFR 870.3460(b). These special controls include specific requirements related to biocompatibility,

sterility and shelf-life, performance testing, MR compatibility, electromagnetic compatibility and electrical safety, labeling, and the prescription-only status of the devices.

SUBSTANTIAL EQUIVALENCE:

The various components of the Heli-FX System covered in this submission are substantially equivalent in materials, method of operation, and intended use as the prior Heli-FX Systems cleared via K102333 and K121168. The devices themselves and their indications for use are identical to those cleared via the aforementioned the submissions; the only differences are in the product packaging. Where specific dimensional and performance differences exist, bench testing has shown that these differences do not present new risks.

DATA RELIED UPON FOR SUBSTANTIAL EQUIVALENCE:

The performance of the modified packaging for the Heli-FX devices was assessed via bench top testing. This testing included visual inspection of the package and product, bubble emission testing, and pouch seal strength on samples that underwent exposure to transportation simulation only, and again following exposure to environmental, transportation, and accelerated aging (two years' equivalent) conditioning. The results of this testing demonstrated that the new packaging is substantially equivalent to the previous packaging.

SUMMARY:

The data and information presented in this application, including bench testing, support a determination of substantial equivalence of the Heli-FX system with modified packaging as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

Aptus Endosystems, Inc.
C/O Burt Goodson
Director, Scientific and Regulatory Affairs
271 Gibraltar Drive
Sunnyvale, CA 94089

Re: K140036
Trade/Device Name: Heli-FX EndoAnchor System
Regulation Number: 21 CFR 870.3460
Regulation Name: Endovascular suturing system
Regulatory Class: Class II
Product Code: OTD
Dated: January 3, 2014
Received: January 7, 2014

Dear Mr. Goodson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Aptus Endosystems, Inc.
271 Gibraltar Dr
Sunnyvale, CA 94089

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): **K140036**

Device Name: Heli-FX EndoAnchor System

Indications for Use: The Heli-FX EndoAnchor System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.

The EndoAnchor may be implanted at the time of the initial endograft placement, or during a secondary (i.e., repair) procedure.

Prescription Use X or Over-the-counter Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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Division sign-off
Division of Cardiovascular Devices

510(k) Number: _____